TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60150763 0001

Report No.: 21234760 013

Manufacturer:

KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products:

- Cannulas for blood collection
- MBU Capillaries
(see attachment for details)

Replaces certificate, Registration No.: HD 60105393 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2020-10-07

Date: 2020-10-07

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60150763 0001
Report No.: 21234760 013

Manufacturer: KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

Products included:

- Cannulas for blood collection

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- MBU Capillaries

Notified Body

Date: 2020-10-07

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

KABE-Labortechnik GmbH
Jägerhofstrasse 17
51588 Nümbrecht
Germany

Contact

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Date July 12, 2024

Notified Body Confirmation Letter
Reference. : KABEL_PLA0HZ_2024-06-18, order #1160753

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

KABE-Labortechnik GmbH
Jägerhofstrasse 17
51588 Nümbrecht
Germany
SRN Number (if available): DE-MF-000011861

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Anja Fechner
2024.07.12 11:14:22
+02'00'

Dipl.-Ing.
Anja Fechner
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BF 21 G grün 200 mm security	IIa	N/A	HD 60150763 0001 NB 0197
BF 22 G schwarz 200 mm security	IIa	N/A	HD 60150763 0001 NB 0197
AM G 46 21G grün 100 mm security	IIa	AM G 46 BF grün 100 mm security	HD 60150763 0001 NB 0197
AM G 46 22G schwarz 100 mm security	IIa	AM G 46 BF schwarz 100 mm security	HD 60150763 0001 NB 0197
AM G 46 21G grün 178 mm security	IIa	AM G 46 BF grün 178 mm security	HD 60150763 0001 NB 0197
AM G 46 22G schwarz 178 mm security	IIa	AM G 46 BF schwarz 178 mm security	HD 60150763 0001 NB 0197
Sangocan® 21G grün 100 mm security	IIa	Sangocan V 21 G grün 100 mm security	HD 60150763 0001 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sangocan® 22G schwarz 100 mm security	IIa	Sangocan V 22 G schwarz 100 mm security	HD 60150763 0001 NB 0197
Sangocan® 21G grün 178 mm security	IIa	Sangocan V 21 G grün 178 mm security	HD 60150763 0001 NB 0197
Sangocan® 22G schwarz 178 mm security	IIa	Sangocan V 22 G schwarz 178 mm security	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün 100 mm security	IIa	Kombi-Sangocan V 21 G grün 100 mm sec.	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün 178 mm security	IIa	Kombi-Sangocan V 21 G grün 178 mm sec.	HD 60150763 0001 NB 0197
Kombi-Sangocan® 22G schwarz 178 mm security	IIa	Kombi-Sangocan V 22 G schwarz 178 mm sec.	HD 60150763 0001 NB 0197
Sangocan V 20 G gelb 100 mm security	IIa	N/A	HD 60150763 0001 NB 0197
AM G 46 20G gelb security	IIa	AM G 46 K gelb security	HD 60150763 0001 NB 0197
AM G 46 21G grün security	IIa	AM G 46 K grün security	HD 60150763 0001 NB 0197
AM G 46 22G schwarz security	IIa	AM G 46 K schwarz security	HD 60150763 0001 NB 0197
Sangocan® 20G gelb security	IIa	Sangocan 20 G gelb security	HD 60150763 0001 NB 0197
Sangocan® 21G grün security	IIa	Sangocan 21 G grün security	HD 60150763 0001 NB 0197
Sangocan® 22G schwarz security	IIa	Sangocan 22 G schwarz security	HD 60150763 0001 NB 0197
Kombi-Sangocan® 20G gelb security	IIa	Kombi-Sangocan 20 G gelb security	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün security	IIa	Kombi-Sangocan 21 G grün security	HD 60150763 0001 NB 0197
Kombi-Sangocan® 22G schwarz security	IIa	Kombi-Sangocan 22 G schwarz security	HD 60150763 0001 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AM G 46 20G gelb	IIa	AM G 46 K gelb	HD 60150763 0001 NB 0197
AM G 46 21G grün	IIa	AM G 46 K grün	HD 60150763 0001 NB 0197
AM G 46 22G schwarz	IIa	AM G 46 K schwarz	HD 60150763 0001 NB 0197
Sangocan® 20G gelb	IIa	Sangocan 20 G gelb	HD 60150763 0001 NB 0197
Sangocan® 21G grün	IIa	Sangocan 21 G grün	HD 60150763 0001 NB 0197
Sangocan® 22G schwarz	IIa	Sangocan 22 G schwarz	HD 60150763 0001 NB 0197
Kombi-Sangocan® 20G gelb	IIa	Kombi-Sangocan 20 G gelb	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün	IIa	Kombi-Sangocan 21 G grün	HD 60150763 0001 NB 0197
Kombi-Sangocan® 21G grün (PT)	IIa	Kombi-Sangocan 21 G grün (0,8 x 25 mm)	HD 60150763 0001 NB 0197
Kombi-Sangocan® 22G schwarz	IIa	Kombi-Sangocan 22 G schwarz	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren 115 µl A-Ø 2,1 mm I-Ø 1,3 mm zu 5 St. verpackt, steril	Is	MBU-Kapillaren 115 µl, AD= 2,1 mm, ID= 1,3 mm, zu 5 Stück verpackt, steril	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren Na 115 mit Kapillarhalter SR 200 steril	Is	NA 115 mit Kapillarhalter SR 200, steril	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren BK 100 dünner Ø balanciertes Heparin mit SR 200 steril	Is	BK 100 dünner Ø neutr. Hep., mit SR 200, steril	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren BK 85 Ø 1,9 x 85 mm balanciertes Heparin *SD* mit SR 200 steril	Is	BK 85 Ø 1,9 x 85 mm neutr. Hep. *SD* mit SR 200, steril	HD 60150763 0001 NB 0197
KABE MBU-Kapillaren BK 110 Ø 1,9 x 110mm balanciertes Heparin *SD* mit SR 200 steril	Is	BK 110 Ø 1,9x110mm neutr. Hep. *SD* mit SR 200, steril	HD 60150763 0001 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
KABE MBU-Kapillaren NH 150 mit Kapillarhalter SR 200 steril	Is	NH 150 mit Kapillarhalter SR 200 steril	HD 60150763 0001 NB 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/07/12	KABEL_CL607_2024-07-12	Initial issue